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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,858	02/18/2005	Sadanobu Shirai	2005_0152A	3564

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EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
06/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/524,858	SHIRAI ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

- Receipt is acknowledged of applicants' remarks, filed on 19 January 2010.
- Applicants' remarks regarding the 35 USC 112 rejection of the previous Office action is persuasive, as such, said rejection is hereby withdrawn.
- Applicants' remarks regarding mineral oil in the Hoffmann reference are persuasive; as such the following is a new ground of rejection.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,254,348 ("Hoffmann") (cited in the IDS of 18 May 2005) in view of U.S. Patent No. 5,866,157 ("Higo") (cited in the PTO-892 of 14 July 2006), further in view of U.S. Patent No. 5,312,627 ("Stroppolo").

Independent claim 1 recites a patch prepared by laminating an adhesive layer consisting of a rubber, an adhesive resin other than an acrylic adhesive, a plasticizer, 1 to 4 w/w % of tulobuterol as an active ingredient and 0.1 to 3 w/w % of a higher fatty acid as a drug-release controlling agent on a backing.

Hoffmann teaches a transdermal therapeutic system comprising tulobuterol (reading on the tulobuterol of claim 1) in a matrix containing at least one polystyrene-

1,3-diene-polystyrene block copolymer (reading on the rubber of claim 1) (see col. 2, lines 55-58) on a backing layer (reading on the backing of claim 1) (see col. 3, line 2). The adhesive matrix may further contain aliphatic hydrocarbon resins (reading on the adhesive resins of claims 1, 2, and 4) (see col. 3, line 41), and glycerol, (reading on the plasticizer of claims 1 and 2) (see col. 3, line 62).

Acrylic adhesives are not required by the Hoffmann invention and are not disclosed in any of the examples.

Hoffmann explains that the disclosed invention is beneficial in that it provides safe dosage of active substance with optimal release rate and tolerance (see col. 2, lines 51-52).

Example 2 of Hoffmann discloses 2% tulobuterol and Example 5 discloses 2.5% tulobuterol, both overlapping with the concentration range recited in claim 1. Example 2 discloses 22% adhesive (copolymers of diolefins and olefins), Example 2a discloses 57% adhesive, and Example 5 discloses 48% adhesive, all overlapping with the concentration range recited in claim 2. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Example 2a discloses 38% rubber (styrene-isoprene-styrene block copolymer). A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected

them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). *See* MPEP 2144.05.

While Hoffman teaches the use of fatty acids in the disclosed composition (see col. 3, lines 58-59), the reference does not explicitly disclose higher fatty acids.

Higo teaches a percutaneous patch formulation for releasing, *inter alia*, tulobuterol (see col. 3, lines 39 and 58). Higo does not require acrylic adhesives and does not disclose them in any of the examples. Higo teaches an adhesive layer comprising, tulobuterol at a concentration of 1-4% (see col. 3, lines 39 and 58), C_{11-22} fatty acids at a concentration of 0.01-20% (see col. 4, line 64 and col. 5, line 24), and rubber at a concentration of 15-60% (see col. 3, line 64 – col. 4, line 9), which overlap with the concentrations recited in claims 1 and 2. It would have been obvious to a person of ordinary skill in the art to modify the teachings of Hoffman with the teachings of Higo to arrive at C_{11-22} fatty acids at a concentration of 0.01-20% since both references teach transdermal formulations comprising, *inter alia*, a low concentration of tulobuterol and fatty acids.

Hoffmann does not disclose percentages for glycerol, however it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges. Plasticizer concentrations overlapping with those being claimed are recognized by the art as result effective variables. Higo teaches plasticizers at a concentration of 10-60% (see col. 4, line 52). Stroppolo teaches plasticizers (e.g. polyethylene glycols) at a concentration of 4-20% (see col. 4, line 53). Stroppolo teaches a transdermal therapeutic system for releasing, *inter alia*, tulobuterol (see col. 4, line 35). Stroppolo does not require acrylic adhesives and does not disclose them in any of the examples.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare a patch consisting of a rubber, an adhesive resin other than an acrylic adhesive, a plasticizer, tulobuterol, and a higher fatty acid, as taught by Hoffmann in view of Higo, further in view of Stroppolo. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it provides safe dosage of active substance with optimal release rate and tolerance, as explained by Hoffmann (see above).

*

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571)272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615